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Clustering of Poor Device Acceptance and Type D Personality is Associated with Increased Distress in Danish Cardioverter-Defibrillator Patients

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Background: Psychosocial risk factors tend to cluster together within individuals, likely enhancing the risk of adverse health outcomes. We examined (1) the influence of clustering of poor device acceptance and Type D personality on anxiety and depressive symptoms, and (2) the demographic and clinical determinants of patients with clustering, in a large cohort of Danish implantable cardioverter defibrillator (ICD) patients.

Methods: Patients ($N = 557$; 81.9% male; mean age = 61.9 ± 14.3 years) implanted with an ICD between 1989 and 2006 were asked to complete a set of standardized and validated questionnaires and were divided into four risk groups: (1) No risk factors (neither poor device acceptance nor Type D), (2) Poor device acceptance only, (3) Type D only, (4) Clustering (both poor device acceptance and Type D).

Results: The prevalence of anxiety was significantly higher in patients with clustering of risk factors (54.2%) compared to patients with poor device acceptance (30.0%), Type D personality (26.5%), or no risk factors (7.6%) ($\chi^2 = 88.472$; $df = 3$; $P < 0.001$). Similarly, the prevalence of depression was higher in the clustering group (47.2%) compared to patients with poor device acceptance (19.1%), Type D personality (23.5%), or no risk factors (1.8%) (Fisher's exact = 112.874; $df = 3$; $P < 0.001$). Patients with the clustering of poor device acceptance and Type D had the highest mean scores of anxiety ($P < 0.001$) and depression (< 0.001), also when adjusting for demographic and clinical baseline characteristics including shocks. Shocks ($P = 0.006$) were associated with increased anxiety but not with depression ($P = 0.31$).

Conclusion: Patients with poor device acceptance and Type D personality should be identified and monitored in clinical practice, as they may benefit from adjunctive intervention in order to experience the same quality of life benefits following implantation as other patients. Given the cross-sectional nature of the study, these findings should be confirmed using a prospective study design. (PACE 2009; 32:29–36)

anxiety, clustering, defibrillator acceptance, depressive symptoms, implantable cardioverter defibrillator, Type D personality

Introduction

Psychosocial risk factors tend to cluster together within individuals, likely enhancing the risk of adverse health outcomes, including increased distress and poor quality of life in patients subject to clustering.¹ However, in patients with cardiovascular disease (CVD), the tendency has been to examine the impact of single psychosocial risk factors,¹ although focusing on the impact of clustering may lead to more accurate risk

estimation in individual patients. Recent Dutch studies of patients treated with percutaneous coronary intervention with drug-eluting stents and patients with an implantable cardioverter defibrillator (ICD) support this notion.^{2,3} In the latter study, the clustering of Type D personality and ICD concerns was shown to incur an increased risk of anxiety 6 months postimplantation compared with the presence of one (i.e., Type D or ICD concerns) or no risk factors, whereas the impact of clustering was less clear for depression.

Type D personality is a potential risk factor in CVD that has been associated both with patient-centered outcomes, such as poor quality of life, but also with adverse clinical events, including mortality and morbidity.^{4–8} Type D personality has also been shown to be of value in arrhythmia research.^{9,10} Type D is defined as the tendency to experience increased negative emotions paired with emotional nonexpression.^{4,5} Patients with this personality disposition typically

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worry, feel down in the dumps, and get easily irritated, while bottling up these negative emotions due to fear of rejection and negative reactions from others.^{4,11}

Personality factors in general and Type D personality in particular may interact with device acceptance to increase the risk of anxiety and depression in ICD patients. Device acceptance can be conceptualized as the psychological accommodation of the device in the patient's life, including a positive view towards the ICD as a life-saving necessity.^{12,13} Previously, device acceptance has been associated with less anxiety, depression, and illness intrusiveness, and better quality of life, but the study did not examine the influence of clustering of poor device acceptance and other psychosocial factors on outcomes.¹² In a recent study of the present sample, we also found that Type D personality was a correlate of poor device acceptance.¹⁴

Hence, in the current study, we examined (1) the influence of clustering of poor device acceptance and Type D personality on anxiety and depressive symptoms, and (2) the demographic and clinical determinants of patients with clustering, in a large cohort of surviving ICD patients implanted at a single center in Denmark.

Methods

Patients and Study Design

Patients implanted with an ICD at Aarhus University Hospital (Skejby), Denmark, since 1989 and still alive on November 1, 2006, comprised the study population. Patients with a first ICD implant within the last 3 months were excluded. The majority of patients (94.8%) had a secondary indication for ICD, since prophylactic implantation was not generally implemented in Denmark prior to 2007. More details of the study design have been published previously.¹⁵ Of 723 eligible patients, 624 (86%) participated.¹⁵ For the current study, analyses were based on 557 patients (81.9% male; mean age = 61.9 ± 14.3 years; mean time since ICD implantation = 4.9 ± 3.2 years) who had complete data on the psychological questionnaires used in the current study.

All surviving patients were informed about the study by mail and asked to complete a self-report questionnaire containing questions on clinical data and standardized and validated psychological questionnaires. If patients did not return the questionnaire within 2 weeks, they were sent a reminder including a duplicate of the questionnaire. The study was conducted to conform to the Helsinki Declaration.

Measures

Demographic and Clinical Variables

Information on demographic (i.e., sex, age, having a partner, education, and working status) and clinical variables (i.e., CVD etiology, cardiac resynchronization therapy, comorbidity, device-related complications, and shocks) and medication (i.e., amiodarone, β -blockers, angiotensin converting enzyme (ACE)-inhibitors, diuretics, thiazide, and psychotropics) were obtained from purpose-designed questions in the questionnaire, the patients' medical records, and the Danish ICD registry.¹⁶ The 21-item Minnesota Living With Heart Failure (MLHF) questionnaire, a disease-specific quality of life measure, was used to derive a proxy for symptomatic heart failure,¹⁷ as information on New York Heart Association (NYHA) functional status was not standardly registered in the Danish ICD registry at the time when it was set up. The MLHF is a valid and reliable measure, with items scored on a 6-point Likert scale from 0 (no) to 5 (very much). The score range is 0–105 for the total scale, with a lower score representing good quality of life. The MLHF score was dichotomized in order to enhance the clinical interpretability,¹⁸ using a cut-off >40 (the 75% upper percentile in our data) to represent NYHA class III–IV (i.e., symptomatic congestive heart failure).¹⁹

Acceptance of the Cardioverter-Defibrillator

The 18-item Florida Patient Acceptance Survey (FPAS) is a disease-specific measure assessing device acceptance.¹³ Items are rated on a 5-point Likert scale from 0 (strongly disagree) to 5 (strongly agree), with a high score indicating more acceptance. Of all items, 15 contribute to four subscales: (1) Return to Function (four items; e.g., *I am confident about my ability to work if I want to*); (2) Device-Related Distress (five items; e.g., *When I think about the device, I avoid doing things that I enjoy*); (3) Positive Appraisal (four items; e.g., *I would receive this device again*); and (4) Body Image Concerns (two items; e.g., *I feel less attractive because of my device*). The remaining three items are filler items. A total score based on the 15 items may also be calculated.¹³ The convergent, divergent, and discriminant validity of the FPAS are good, and the scale has been shown to be internally consistent, as indicated by Cronbach's α ranging from 0.74 to 0.83.¹³ The validity and reliability of the Danish version of the FPAS was recently confirmed in the present cohort of ICD patients, with device acceptance as assessed by the total score on the FPAS correlating inversely with anxiety ($r = -0.53$) and depressive symptoms ($r = -0.57$).¹⁴ These correlations, with

a shared variance of only 28–32%, indicate that device acceptance is conceptually different from measures of anxiety and depressive symptoms, despite some overlap. In the current study, we only used the total FPAS score.

Type D Personality

The 14-item Type D Scale (DS14) was used to assess Type D personality, which is a normal personality taxonomy developed in cardiac patients.^{4,11} The DS14 consists of two 7-item subscales, that is, negative affectivity (e.g., *I often feel unhappy*) and social inhibition (e.g., *I am a closed kind of person*).¹¹ Items are answered on a five-point Likert scale ranging from 0 (false) to 4 (true), with a score range from 0 to 28 for both subscales. A standardized cut-off ≥ 10 on both subscales is used to categorize patients as having a Type D personality,¹¹ with this cut-off being the most optimal as confirmed by item response theory.²⁰ It is the combination of the two personality traits (i.e., negative affectivity and social inhibition) rather than the single traits that incurs an increased risk of adverse clinical events.⁶ Type D is not confounded by disease severity,^{21,22} and has in patients with acute myocardial infarction been shown to be stable during an 18-month period.²¹ The psychometric properties of the scale are good, with Cronbach's α of 0.88/0.86 and 3-month test-retest reliability $r = 0.72/0.82$ for the negative affectivity and social inhibition subscales, respectively.¹¹

Anxiety and Depressive Symptoms

The 14-item Hospital Anxiety and Depression Scale (HADS)[®] was used to assess symptoms of anxiety and depression.²³ The HADS is comprised of two subscales (i.e., a seven-item anxiety and a seven-item depression subscale). Items are answered on a four-point Likert scale from 0 to 3, with a score range from 0 to 21 for each subscale. A cut-off score ≥ 8 has been shown to provide the most optimal balance between sensitivity and specificity.²⁴ Hence, we used this cut-off in the current study to indicate probable clinical levels of anxiety and depression. The HADS is a valid and reliable instrument that has been used across the world in cardiac and noncardiac populations, including in outpatients.^{24,25} An advantage of the HADS is that it is devoid of somatic symptoms, decreasing the likelihood that probable clinical levels of anxiety and depression are inflated in somatic patients.²⁵

Statistical Analyses

Prior to statistical analyses, patient scores on the FPAS were dichotomized using the lowest tertile to indicate poor device acceptance. FPAS was

dichotomized in order to be consistent with a previous study of the current sample that used the same cut-off on the FPAS.¹⁴ Subsequently, we created four risk groups, based on device acceptance and Type D personality, as follows: (1) No risk factors (neither poor device acceptance nor Type D; $n = 341$; 61.2%), (2) Poor device acceptance only ($n = 110$; 19.7%), (3) Type D only ($n = 34$; 6.1%), and (4) Clustering (both poor acceptance and Type D; $n = 72$; 12.9%). The percentage of patients in each group does not add up to 100% due to rounding. The χ^2 test (Fisher's exact test when appropriate) was used to examine differences between the four risk groups on nominal baseline characteristics and analysis of variance (ANOVA), with a post hoc Bonferroni correction, on continuous characteristics. ANOVA with a post hoc Bonferroni correction was also used to compare the four risk groups on mean scores of anxiety and depression. To rule out the potentially confounding effects of demographic and clinical characteristics on the influence of the four risk groups on anxiety and depression, respectively, analysis of covariance (ANCOVA) was used, adjusting for all baseline characteristics, as presented in Table I.

In a subsequent analysis, using logistic regression analysis, we examined whether patients subject to risk factor clustering differed from the other three groups (i.e., those with one or no risk factors) on demographic and clinical characteristics. Hence, prior to these analyses, the three groups with one or no risk factors were merged into one and used as reference category for the clustering group. Given that the sample size in the clustering group was 72 and in order to avoid overfitting of the regression model, we first conducted a series of univariable logistic regression analyses, and chose to include in the multivariable model only those characteristics listed in Table I that were significant at <0.05 . All tests were two-tailed. A P -value <0.05 was used to indicate statistical significance. All analyses were performed using SPSS 14.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Study Participants Versus Nonparticipants on Baseline Characteristics

Patients ($n = 557$) included in the analyses did not differ systematically from nonparticipants and those with incomplete psychological data for the current study ($n = 166$) on gender, age, coronary artery disease (CAD) etiology, cardiac resynchronization therapy defibrillator (CRT-D), and device-related complications (results not shown). However, patients included in the analyses were more likely to have had their ICD for fewer years compared to nonparticipants and those with

Table I.
Baseline Patient Characteristics Stratified by Risk Groups*

	None (n = 341)	Poor Device Acceptance (n = 110)	Type D (n = 34)	Clustering (n = 72)	P
Demographics					
Female gender	18.5 (63)	16.4 (18)	20.6 (7)	18.1 (13)	0.94
Age ^a	60.3 (14.9) [#]	64.0 (12.3)	60.5 (16.3)	66.6 (11.8) [#]	0.002
Partner/living together	79.8 (272)	69.1 (76)	82.4 (28)	73.6 (53)	0.06
Education ^b	27.0 (92)	15.5 (17)	14.7 (5)	13.9 (10)	0.01
Working	34.6 (118)	15.5 (17)	17.6 (6)	4.2 (3)	<0.001
Clinical					
Nonischemic etiology	41.1 (140)	37.3 (41)	35.3 (12)	31.9 (23)	0.49
Symptomatic heart failure ^c	10.9 (37)	47.3 (52)	17.6 (6)	56.9 (41)	<0.001
CRT-D	17.0 (58)	22.7 (25)	8.8 (3)	23.6 (17)	0.16
Comorbidity ^d	19.6 (67)	26.4 (29)	17.6 (6)	27.8 (20)	0.22
Device-related complications	8.5 (29)	9.1 (10)	2.9 (1)	8.3 (6)	0.78
Shocks	42.8 (146)	41.8 (46)	32.4 (11)	47.2 (34)	0.50
Years since implantation ^a	4.8 (3.2)	4.3 (3.3)	4.5 (3.2)	4.9 (3.1)	0.46
Medication					
Amiodarone	19.4 (66)	28.2 (31)	14.7 (5)	40.3 (29)	0.001
β -blockers	81.2 (277)	81.1 (90)	73.5 (25)	76.4 (55)	0.90
ACE-inhibitors	65.7 (224)	77.3 (85)	58.8 (20)	59.7 (43)	0.08
Diuretics	39.9 (136)	54.5 (60)	32.4 (11)	56.9 (41)	0.004
Thiazide	9.4 (32)	10.0 (11)	11.8 (4)	6.9 (5)	0.83
Psychotropic medication	9.7 (33)	14.5 (16)	11.8 (4)	27.8 (20)	0.001

* Presented as % (n) unless otherwise indicated.

[#] Post hoc Bonferroni correction was significant between the two groups ($P = 0.004$).

^a Presented as mean (\pm SD).

^b > 9 years.

^c Based on the 75th percentile on the Minnesota Living with Heart Failure Questionnaire,¹⁷ which was MLHF > 40 in the current study.

^d For example, cancer.

CRT-D = cardiac resynchronization therapy with an ICD.

incomplete data (4.68 ± 3.24 vs 5.49 ± 3.62 ; $P = 0.006$).

Baseline Characteristics

Baseline characteristics stratified by the four risk groups, based on device acceptance and Type D personality, are shown in Table I. The risk groups differed significantly on age ($P = 0.002$), education ($P = 0.01$), working status ($P < 0.001$), the presence of symptomatic heart failure ($P < 0.001$), the use of amiodarone ($P = 0.001$), diuretics ($P = 0.004$), and psychotropic medication ($P = 0.001$), with patients with the clustering of poor device acceptance and Type D personality being older; having lower education; less likely to be working; and more likely to have symptomatic heart failure, to take amiodarone, diuretics, and psychotropic medication compared to the other three groups.

Prevalence of Anxiety and Depression, Stratified by Device Acceptance and Personality

The overall prevalence of probable clinical levels of anxiety and depression, as defined by a cut-off of ≥ 8 on the HADS,²⁴ was 19.2% (95% CI: 16.2%–22.7%) and 12.4% (95% CI: 9.9%–15.4%), respectively. The prevalence rates for probable anxiety and depression with their corresponding 95% confidence intervals, stratified by device acceptance and Type D personality, are presented in Figure 1. The prevalence of anxiety was significantly higher in patients with clustering of risk factors (54.2%; 95% CI: 42.7%–65.2%) compared to patients with poor device acceptance only (30.0%; 95% CI: 22.2%–39.1%), Type D personality only (26.5%; 95% CI: 14.6%–43.1%), or no risk factors (7.6%; 95% CI: 5.3%–10.9%) ($\chi^2 = 88.472$; $df = 3$; $P < 0.001$). Similarly, the prevalence of depression was higher in the clustering group (47.2%; 95% CI: 36.1% – 58.6%) compared to patients with poor

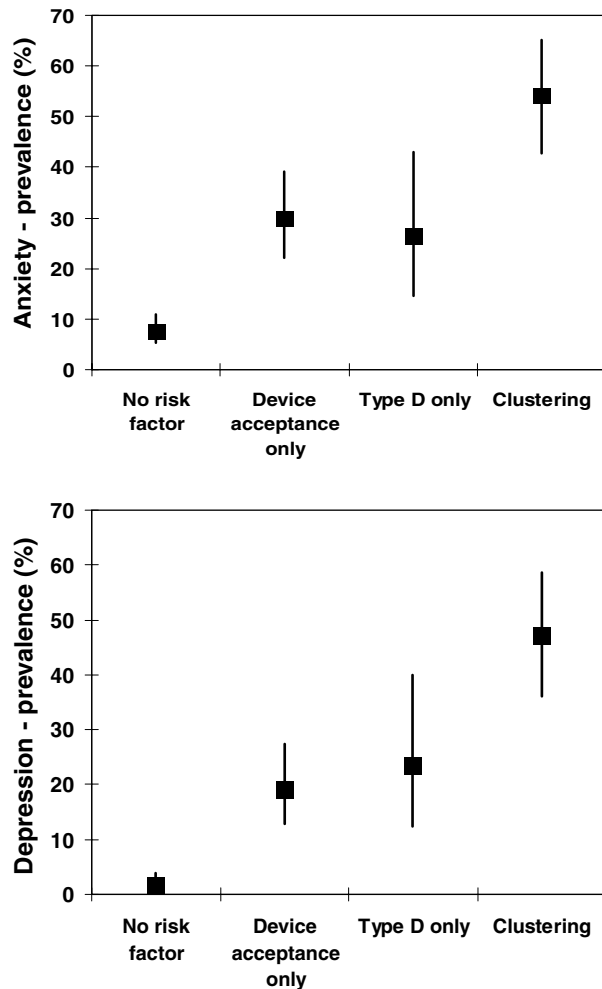


Figure 1. Prevalence rates for probable anxiety and depression (the prevalence of symptoms of anxiety and depression was determined with the standardized cut-off ≥ 8 on the Hospital Anxiety and Depression Scale [24], indicating probable clinical levels but not a clinical diagnosis of anxiety and depression) with their corresponding 95% confidence intervals, stratified by device acceptance and Type D personality.

device acceptance only (19.1%; 95% CI: 12.8%–27.4%), Type D personality only (23.5%; 95% CI: 12.4%–40.0%), or no risk factors (1.8%; 95% CI: 0.8%–3.8%) (Fisher's exact = 112.874; df = 3; $P < 0.001$).

Mean Anxiety and Depression Scores, Stratified by Device Acceptance and Personality (unadjusted)

Dichotomization of outcome measures has been advocated in order to enhance the clinical interpretability and applicability of the results,¹⁸ but from a statistical point of view dichotomiza-

tion may lead to the loss of information. Hence, in order to confirm the differential associations found for the four risk groups in relation to the prevalence of anxiety and depression, we also performed ANOVAs using continuous scores on the HADS.

The results found in relation to the prevalence rates were confirmed using continuous scores, with levels of anxiety being highest in patients with clustering of poor device acceptance and Type D (mean = 8.40 ± 4.25), with scores in patients with poor device acceptance only (mean = 5.91 ± 3.86) and Type D only (mean = 5.10 ± 3.80) being almost equal, followed by the no-risk factor group (mean = 2.71 ± 2.99) who had the lowest scores ($F(3,553) = 69.780$; $P < 0.001$). The findings were similar for depression, with levels of depression being highest in patients with clustering of poor device acceptance and Type D (mean = 7.25 ± 3.52), with scores in patients with poor device acceptance only (mean = 4.96 ± 3.11) and Type D only (mean = 5.41 ± 3.48) being almost equal, followed by the no-risk factor group (mean = 1.70 ± 1.88) who had the lowest scores ($F(3,553) = 127.625$; $P < 0.001$). For both anxiety and depression, all post hoc comparisons were statistically significant except for mean differences between the poor device acceptance only and Type D only groups.

Mean Anxiety and Depression Scores, Stratified by Device Acceptance and Personality (Adjusted)

To rule out that the influence of clustering of device acceptance and Type D personality on anxiety and depression could be attributed to confounders, we ran ANCOVAs adjusting for gender, age, having a partner, education, working status, CAD etiology, symptomatic heart failure, CRT-D, comorbidity, device-related complications, shocks, years since implantation, and medication (i.e., amiodarone, β -blockers, ACE-inhibitors, diuretics, thiazide, and psychotropics).

In adjusted analysis, the influence of clustering of device acceptance and Type D personality on anxiety was still statistically significant ($F(3,437) = 36.242$; $P < 0.001$). Female gender ($F(1,437) = 10.102$; $P = 0.002$), symptomatic heart failure ($F(1,437) = 11.483$; $P = 0.001$), shocks ($F(1,437) = 7.679$; $P = 0.006$), and the use of psychotropic medication ($F(1,437) = 6.225$; $P = 0.01$) were also independently associated with anxiety, whereas none of the other covariates were significant (all P s > 0.05). The model accounted for 34% (adjusted R^2) of the variance in anxiety.

Similarly, the influence of clustering of device acceptance and Type D personality on depressive symptoms was still statistically significant ($F(3,437) = 50.772$; $P < 0.001$) in adjusted analysis.

Other independent associates were symptomatic heart failure ($F(1,437) = 27.246$; $P < 0.001$) and the use of psychotropic medication ($F(1,437) = 8.533$; $P = 0.004$). Shocks were not a significant correlate of depression ($F(1,437) = 1.022$; $P = 0.31$) nor were any of the other covariates (all P s > 0.05). The model accounted for 42% (adjusted R^2) of the variance in depression.

Determinants of Clustering of Poor Device Acceptance and Type D Personality

Given that patients with clustering of poor device and Type D personality were more likely to be anxious and depressed compared to patients with one or no risk factors, we examined whether patients subject to risk factor clustering differed from the other three groups on demographic and clinical characteristics. Knowledge of the demographic and clinical determinants of clustering is important in order to be able to identify these high-risk patients in clinical practice.

All baseline characteristics listed in Table I were entered as potential determinants of clustering in separate logistic regression analyses. Only age; working status; symptomatic heart failure; and the use of amiodarone, diuretics, and psychotropic medication were statistically significant determinants of clustering (all P s < 0.05 ; results not shown). Subsequently, these variables were entered together in a multivariable logistic regression analysis. Patients with clustering of poor device acceptance and Type D personality were less likely to be working (OR: 0.14; 95% CI: 0.03–0.67), and more likely to have symptomatic heart failure (OR: 4.15; 95% CI: 2.26–7.62) and use psychotropic medication (OR: 2.18; 95% CI: 1.14–4.17) compared to patients with one or no risk

factors (Table II). Although the use of amiodarone was not statistically significant, there was a clear trend for patients with clustering being more likely to be prescribed amiodarone (OR: 1.86; 95% CI: 1.00–3.46).

Discussion

A paucity of studies have examined the impact of clustering of psychosocial risk factors on patient-centered outcomes in CVD in general and patients treated with ICD therapy in particular, despite that a focus on clustering may lead to a more accurate risk estimation in individual patients. In the current study of a large cohort of surviving ICD patients implanted at a single center in Denmark, we focused on the clustering of two psychosocial factors (i.e., device acceptance and Type D personality) that have separately been associated with psychological distress and poor quality of life in ICD patients. Previously, device acceptance has been linked to decreased anxiety and depression and better quality of life,¹² whereas Type D has been shown to increase psychological distress and predict poor quality of life.^{9,10} Recently, we also found that Type D personality was a correlate of poor device acceptance, as measured by the FPAS.¹⁴

In the current study, the clustering of poor device acceptance and Type D personality was associated with the highest levels of anxiety and depression compared to groups with one or none of these risk factors. These results remained unchanged, adjusting for baseline and clinical characteristics including shocks. These findings are consistent with the results of recent Dutch studies of percutaneous coronary intervention patients² and ICD patients.³ In the latter study, the clustering of Type D personality and ICD concerns (i.e., concerns about the ICD giving a shock) was associated with the highest levels of anxiety compared to the presence of one or no risk factors, although the influence of clustering was less clear for depression.³

The findings of our study also support the notion that the ICD is generally well tolerated by the majority of patients, with clinical levels of anxiety and depression only occurring in a subset of patients, and with the prevalence rates in our study (12–19%) being well below those reported (25–33%) in reviews of psychosocial adaptation to ICD therapy.^{26,27} These differences in prevalence rates may in part be attributed to the cross-sectional design of our study and patients being implanted with their ICD a mean of 4.9 years ago, with the likelihood that anxiety and depression levels may have decreased in our cohort of patients compared to, e.g., the first 6–12 months following implantation. Generally, patients experience

Table II.

Determinants of Clustering of Poor Device Acceptance and Type D Personality*

	OR	[95% CI]	P
Age	1.00	[0.97–1.03]	0.73
Working	0.14	[0.03–0.67]	0.01
Symptomatic heart failure ^a	4.15	[2.26–7.62]	<0.001
Amiodarone	1.86	[1.00–3.46]	0.05
Diuretics	0.78	[0.42–1.46]	0.44
Psychotropic medication	2.18	[1.14–4.17]	0.02

*Logistic regression analysis (multivariable), using a merging of one or no risk factors as the reference category.

^aBased on the 75th percentile on the Minnesota Living with Heart Failure Questionnaire,¹⁷ which was MLHF > 40 in the current study.

improvements in quality of life and a decrease in distress in the first year following implantation, likely due to adaptation to living with an ICD.^{3,10,26} Although shocks were a statistically significant associate of anxiety in the current study, shocks were not related to depressive symptoms. Similarly, in a previous study of the current sample focusing on device acceptance as the outcome, shocks were not significantly related to acceptance of the ICD, with device acceptance being better predicted by the psychological profile of the patient and the presence of symptomatic heart failure,¹⁴ which has also been found by others.¹² This begs the question whether we should start looking beyond shocks to also examine the role of a wide range of psychological factors, as previously posited.¹⁴

In clinical practice, it is worthwhile to identify patients at risk of psychosocial risk factor clustering due to their increased levels of psychological distress and adverse health outcomes, as shown in this cohort of Danish patients and other studies of Dutch patients.^{2,3} In the current sample, patients who were not working, had symptomatic heart failure, and who were prescribed amiodarone and used psychotropic medication were more likely to be at risk for clustering. Hence, health care providers should be particularly alert when seeing patients with this profile in clinical practice, as they are at risk for clustering of psychosocial risk factors and increased psychological distress. In addition to looking at their clinical and socio-demographic profile, the FPAS and Type D Scale could be administered as screening tools in clinical practice. If patients are confirmed both to have poor device acceptance and a Type D personality, they should be offered adjunctive intervention either to prevent the onset of anxiety and depression, or to reduce levels of distress, if already manifest, in order to improve their quality of life.^{28,29} Such intervention should target the psychological profile of patients, incorporating a cognitive behavioral component, but also education about the ICD; what to expect from the ICD, including shocks; and how to cope with the unique features of the ICD (e.g., teaching patients to have a shock plan), as this may serve to lessen the impact of shocks on patient-centered outcomes.²⁹ In combination with cardiac rehabilitation, this may be the best approach for countering the manifestation of psychological distress.³⁰ Focusing on these high-risk patients, which form 19.7% in the current study, may also be more cost-effective from the point of view of offering adjunctive intervention to those patients who need it the most.

The results of the current study should be interpreted with some caution, as patients included in the analyses differed from nonparticipants and those with incomplete psychological data on number of years since implantation, with those in-

cluded in the analyses having had their ICD for a shorter period of time. In addition, the third risk group (i.e., Type D only) was based on a relatively small number of patients ($n = 34$), and the study design was cross-sectional, which makes it impossible to draw causal inferences. Moreover, we had no information on disease severity, such as left ventricular ejection fraction (LVEF), changes in medication, and worsening of heart failure, which might have influenced outcome, as this information was not listed standardly in the Danish ICD registry.¹⁶ However, previous studies found no influence of LVEF on patient-centered outcomes, such as anxiety, depression, and quality of life.^{3,10} Information on some of the clinical variables was also based on self-report, which may be subject to bias. In addition, the majority of the sample (i.e., 94.8%) was comprised of secondary prevention patients, with the results not necessarily generalizing to primary prevention patients, even though there is no evidence to date to indicate that indication for ICD may impact on patient-centered outcomes.^{10,31,32} Finally, all psychological measures were self-report rather than interview-based. Nevertheless, all questionnaires were standardized and validated and included both generic and disease-specific measures.

In conclusion, patients with clustering of poor device acceptance and Type D personality reported the highest levels of anxiety and depression compared to groups with one or none of these risk factors. These results remained unchanged, adjusting for baseline and clinical characteristics including shocks. Patients who were subject to clustering were more likely to have symptomatic heart failure, not to be working, and to be prescribed amiodarone and psychotropic medication. Although these findings should be confirmed using a prospective study design, it may be timely to shift from studying the influence of single risk factors on patient-centered outcomes, even though analyses may adjust for other psychosocial risk factors, as focusing on clustering may provide a more realistic picture of the risk to patients. If the findings of the current study are confirmed in future research, patients with a Type D personality and poor acceptance of their device should be identified and monitored in clinical practice, as they may benefit from adjunctive intervention that includes a psychosocial component in order to reduce symptoms of anxiety and depression, such that they experience the same quality of life benefits following implantation as other patients. An advantage of using the FPAS compared to measures of anxiety and depression in future studies in ICD patients is that the FPAS is applicable to all patients, whereas measures of anxiety and depression are only relevant to a subgroup.

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